REMARKS/ARGUMENTS

In response to the Office Action mailed March 17, 2004, Applicants amend their application and request reconsideration in view of the amendments. In this amendment, Claim 1 is amended, no claims have been cancelled and no claims have been added so that Claims 1-8, 16 and 17 are currently pending. No new matter has been introduced.

The criticality of a "powder" for preventing the agent from separating that the Examiner suggests is lacking is set forth on page 26, line 31 to page 27, line 20 and repeated below.

> "A related problem occurs in medical devices such as stents. In the drug-coated stents crimped state, some struts come into contact with each other and when the stent is expanded, the motion causes the polymeric coating comprising the drugs, agents or compounds to stick and stretch. This action may potentially cause the coating to separate from the stent in certain areas. The predominant mechanism of the coating self-adhesion is believed to be due to mechanical forces. When the polymer comes in contact with itself, its chains can tangle causing the mechanical bond, similar to Velcro®. Certain polymers do not bond with each other, for example, fluoropolymers. For other polymers, however, powders may be utilized. In other words, a powder may be applied to the one or more polymers incorporating the drugs, agents or other compounds on the surfaces of the medical device to reduce the mechanical bond. Any suitable biocompatible material which does not interfere with the drugs, agents, compounds or materials utilized to immobilize the drugs, agents or compounds onto the medical device may be utilized. For example, a dusting with a water-soluble powder may reduce the tackiness of the coatings surface and this will prevent the polymer from sticking to itself thereby reducing the potential for delamination. The powder should be water- soluble so that it does not present an emboli risk. The powder may comprise an anti-oxidant, such as vitamin C, or it may comprise an anti-

> coagulant, such as aspirin or heparin. An advantage of utilizing an anti-oxidant may be in the fact that the anti-oxidant may preserve the other drugs, agents or compounds over longer periods of time."

As may be seen from a reading of the paragraph, a powder may be applied to the polymer so that it becomes less tacky and reduces the chances of the coating from separating from the device by self-adhesion. Also, it is set forth that the powder be water soluble and that it may comprise an anti-oxidant such as vitamin C or an anti-coagulant, such as aspirin or heparin. Accordingly, any material that prevents separation cannot be considered an equivalent. Surely, waxes cannot be considered powders nor can silicones or polymeric materials.

Claims 1-8, 16 and 17 were rejected as being unpatentable over U.S. Patent Application Publication Number 2002/0041899 to Chudzik et al. (Chudzik). This rejection is respectfully traversed.

Chudzik discloses a coating composition for use in delivering a medicament from the surface of a medical device positioned *in vivo*. Medicaments include a wide range of biologically active materials or drugs. A wide range of drugs and/or agents are set forth in the disclosure. Medical devices include a wide range of implantable and removable devices such as vascular stents and grafts. The medicament is typically incorporated into a polymeric matrix after the matrix itself has been coated onto a medical device. Essentially, the medical device is soaked in a medicament solution wherein it is absorbed into the matrix and the device is air dried. In certain embodiments, another polymer layer comprising the same or different polymer than that of the base layer can be affixed to the device. The medicament layer can pass through this topcoat. This method of using the second polymer layer allows for a more lubricious device according to the disclosure.

The present invention, as claimed in amended independent Claim 1, is directed to a local drug delivery device which comprises a medical device for implantation into a treatment site of a living organism, a layer including at least one agent in therapeutic dosages incorporated in a

polymeric matrix and affixed to the medical device for the treatment of reaction by the living organism caused by the medical device or the implantation thereof, and a water soluble powder for preventing the at least one agent from separating from the medical device prior to implantation. The water-soluble powder being affixed to the layer affixed to the medical device.

The MPEP, in section 706.02(j), sets forth the basic criteria that must be met in order to establish a *prima facie* case of obviousness.

> "To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure. In re Vaeck, 947 F.2d,488,20 USPQ2d 1438 (Fed.Cir. 1991). See MPEP § 2143 - § 2143.03 for decisions pertinent to each of these criteria."

Section 2143.03 of the MPEP clarifies certain criteria in section 706.02(j).

> "To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1074). "All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending

therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)."

It is respectfully submitted that Chudzik fails to disclose a water-soluble powder affixed to the polymeric coating comprising a therapeutic dosage of an agent for treating certain reactions. What Chudzik discloses is a method for creating a lubricious coating onto a drug/polymer matrix as set forth in paragraph 0080 of Chudzik. The method involves the use of the same or different polymer, in solution form, to be affixed to the device and basecoat. Chudzik only discusses polymers for adding lubriciousness. Chudzik fails to disclose or even remotely suggest the use of a water-soluble powder that potentially makes a polymer less "sticky." As set forth above, silicones, waxes and polymers are not the equivalent of powder forms of vitamin C and aspirin. Therefore, since Chudzik fails to suggest all of the claimed elements, there is no *prima facie* obviousness. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

A favorable action on the merits is earnestly solicited.

Respectfully submitted,

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